

WE CLAIM:

1. An oral pharmaceutical composition comprising:
 - a) nateglinide or pharmaceutically acceptable salts thereof; and
 - b) a water-soluble filler at a concentration range of 50-70% w/w of the composition.
2. The oral pharmaceutical composition according to claim 1, wherein at least 70% by weight of the nateglinide is released within 45 minutes in 1000 ml, 0.01 N HCl, with 0.5% SLS (pH=1.2), using USP apparatus – II, at 50 rpm.
3. The oral pharmaceutical composition according to claim 1, wherein the water-soluble filler comprises one or more of lactose, white sugar, sucrose, glucose, sorbitol and mixtures thereof.
4. The oral pharmaceutical composition according to claim 3, wherein the water-soluble filler comprises lactose.
5. The oral pharmaceutical composition according to claim 1, further comprising one or more pharmaceutically acceptable excipients.
6. The oral pharmaceutical composition according to claim 5, wherein the one or more pharmaceutically acceptable excipients comprise one or more of binders, disintegrants, lubricants, and coloring and flavoring agents.
7. The oral pharmaceutical composition according to claim 6, wherein the binder comprises one or more of methyl cellulose, hydroxypropyl cellulose, hydroxy propyl methyl cellulose, povidone, gelatin, gum Arabic, ethyl cellulose, polyvinyl alcohol, pullulan, pregelatinized starch, agar, tragacanth, sodium alginate, propylene glycol, and mixtures thereof.
8. The oral pharmaceutical composition according to claim 7, wherein the binder comprises povidone.
9. The oral pharmaceutical composition according to claim 6, wherein the disintegrant comprises one or more of starch, croscarmellose sodium, crospovidone, sodium starch glycolate, polacrillin potassium and mixtures thereof.
10. The oral pharmaceutical composition according to claim 9, wherein the disintegrant comprises croscarmellose sodium.

- 1 11. The oral pharmaceutical composition according to claim 6, wherein the lubricant
2 comprises one or more of colloidal anhydrous silica, stearic acid, magnesium stearate,
3 calcium stearate, talc, hydrogenated castor oil, sucrose esters of fatty acids,
4 microcrystalline wax, yellow beeswax, and white beeswax.
- 1 12. The oral pharmaceutical composition according to claim 11, wherein the lubricant
2 comprises magnesium stearate.
- 1 13. The oral pharmaceutical composition according to claim 1, wherein the
2 pharmaceutical composition comprises a tablet or capsule.
- 1 14. The oral pharmaceutical composition according to claim 13, wherein the tablet is
2 coated with one or more functional and/or non-functional layers.
- 1 15. The oral pharmaceutical composition according to claim 1, further comprising one
2 or more channeling agents.
- 1 16. The oral pharmaceutical composition according to claim 15, wherein the
2 channeling agent comprises one or more of a sugar, a salt or a sugar alcohol, or
3 combinations thereof.
- 1 17. The oral pharmaceutical composition according to claim 16, wherein the sugar
2 comprises one or more of compressible sugar, glucose, and mannose.
- 1 18. The oral pharmaceutical composition according to claim 16, wherein the salt
2 comprises one or more of sodium chloride, and potassium chloride.
- 1 19. The oral pharmaceutical composition according to claim 16, wherein the sugar
2 alcohol comprises one or more of mannitol, sorbitol, xylitol, erythritol, lactitol, and
3 maltitol.
- 1 20. The oral pharmaceutical composition according to claim 15, wherein the
2 channeling agent comprises compressible sugar.
- 1 21. The oral pharmaceutical composition according to claim 15, wherein the
2 channeling agent comprises sodium chloride.
- 1 22. A process for preparation of an oral pharmaceutical composition of nateglinide, the
2 process comprising:
- 3 a) blending nateglinide, disintegrant, and a water soluble filler to
4 form a blend;

- 5 b) granulating the blend with a binder solution;
6 c) drying and sizing the granules; and
7 d) lubricating and compressing the lubricated granules to form an
8 oral pharmaceutical composition, wherein the water soluble filler
9 is present at a concentration of 50% to 70% w/w of the oral
10 pharmaceutical composition.
- 1 23. The process according to claim 22, further comprising blending a channeling agent
2 with the nateglinide, disintegrant, and water soluble filler to form the blend.
- 1 24. The process according to claim 22, wherein the granulation comprises wet
2 granulation or dry granulation.
- 1 25. The process according to claim 22, wherein the binder solution comprises a binder
2 and a solvent.
- 1 26. The process according to claim 25, wherein the solvent comprises one or more of
2 methylene chloride, isopropyl alcohol, acetone, methanol, ethanol, and water.
- 1 27. The process according to claim 22, wherein the blend further comprises one or
2 more pharmaceutically acceptable excipients.
- 1 28. The process according to claim 22, wherein the pharmaceutically acceptable
2 excipients comprise one or more of binders, disintegrants, lubricants, coloring and
3 flavoring agents.
- 1 29. A method for the treatment of metabolic disorders, type 2 diabetes mellitus, or a
2 disease or condition associated with diabetes mellitus, the method comprising
3 administering to a patient in need thereof a pharmaceutical composition comprising:
4 a) nateglinide or pharmaceutically acceptable salts thereof; and
5 b) a water-soluble filler at a concentration range of 50-70% w/w of the
6 composition.
- 1 30. The method according to claim 29, wherein the pharmaceutical composition
2 administered further comprises a channeling agent.
- 1 31. The method according to claim 29, wherein at least 70% by weight of the
2 nateglinide is released within 45 minutes in 1000 ml, 0.01 N HCl, with 0.5% SLS (pH-
3 1.2), using USP apparatus – II, at 50 rpm.